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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/406,575 | 09/24/1999 | THOMAS J. BACHINSKI | 293/008-CONT | 1763 |

7590 08/13/2003
ROBERT R JACKSON
FISH & NEAVE
1251 AVENUE OF THE AMERICAS
NEW YORK, NY 10020

EXAMINER

PREBILIC, PAUL B

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3738

DATE MAILED: 08/13/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|----------------------------------|--|
| Office Action Summary | Application No. 09/406,575 | Applicant(s) BACHINSKI ET AL. | |
| | Examiner Paul B. Prebilio | Art Unit 3738 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-147 is/are pending in the application.
- 4a) Of the above claim(s) 25, 27-43 and 95-143 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26, 44-94 and 144-147 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 30, 2003 has been entered.

Claims 25, 27-43, and 95-143 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions there being no allowable generic or linking claim. Election was made **without** traverse by original presentation.

With regard to the new filed claims 144 to 147, the Examiner did not find clear support of the subject matter from the original disclosure and Applicants did not point out where such support was found; see MPEP 714.02 and 2163.06 which are incorporated herein by reference thereto. The Examiner respectfully requests that Applicant particular point out where there is original support for these claims in the response to this Office action.

With regard to the copying of claims from WIPO documents, the statute 35 USC 135 does not provide for interference between WIPO patents and US Patent Applications. It only provides for interference between US Patent Applications or between US Patents and US Patent Applications. For this reason, even though copies of WIPO claims were made and 37 CFR 1.604(b) cited in the response filed May 30,

2003, an interference will not be set up until only US Patent or Applications claims are copied and those claims are found allowable.

Information Disclosure Statement

The information disclosure statement filed May 30, 2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

The information disclosure statement filed May 30, 2003 fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office. It has been placed in the application file, but the information referred to therein has not been considered. Since no PTO-1449 or equivalent was provided with the information disclosure statement, no uninitialed copy of that form could be provided with this Office action.

Claim Objections

Claims 46-52, 65-75, and 78-79 are objected as having the same scope. In particular, each of claims 46-52 have a scope, which is identical to each other. Each of claims 65-68 has an identical scope to the other. Claims 69-72 all have the same scope. Claims 73-75 all have the same scope, and claims 78 and 79 have the same scope. If these claims are allowed, Applicant will be required to cancel all but one of the duplicate claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26, 44-94 and 145-146 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 26 and 44-94, the phrase "cylinder-like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "cylinder-like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d). For this reason, the phrase "cylinder-like" will be interpreted to mean "cylinder."

With regard to claim 145, the terminology "said segments" is indefinite based upon the base claim because two segments were previously set forth therein.

With regard to claim 146, the terminology "said attachment segment" lacks antecedent basis from the base claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26, 44-58, 63-94, and 144-147 are rejected under 35 U.S.C. 102(b) as being anticipated by Marin et al (US 5,397,555). Marin et al meets the claim language

where the barbs (18) twist about ribs (14) to engage the tissue to the extent required by the claim language; see Figures 1 and 2 as well as column 2, line 39 to column 3, line 15.

With regard to claim 44, since the barbs (18) of Marin are spikes and are along the longitudinal axis of Marin's device, the barbs (18) inherently are capable of engaging two blood vessels depending upon how the device is used.

With regard to claims 81 and 82, since the spikes are arranged at different axial locations along the device, if the device was first expanded on one end prior to the other end being expanded, then the spikes would extend sequentially.

With regard to claim 86, the pinching action claimed is an intended use of method of use limitation. Nonetheless, this pinching action would occur in the Marin device to the extent required because the axial length would shorten as the device is radially expanded such that the tissue between the barbs would get pinched.

With regard to claim 91, the material and the plastic limit of the cells would act to control the expansion and thus the strut would act as restraining elements to the extent required.

With regard to claims 144-147, the claim language is fully met where the clip segments as claimed are made of each ring of diamond shaped elements of Marin (see Figure 2), the twistable segments as claimed are the ribs (14) of Marin which twist upon expansion. The segments that are bendable out of the plane to penetrate tissue are not designed to transfix that tissue only to hold the stent in place.

With regard to claim 147, the clip segments as claimed contain the twistable segments where the barbs project outwardly therefrom to penetrate tissue. For this reason, the claim language is fully met with this modified interpretation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 59-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marin et al (US 5,397,555) in view of Frantzen et al (US 5,843,164). Marin meets the claim language as set forth above but lacks the super-elastic temperature-triggered shape-memory material for the device as claimed. However, Nitinol has all these claimed properties and has been known and used in the art prior to the invention as a substitute for Palmaz stainless steel materials; see Frantzen on column 2, lines 36-55 and see Marin et al on column 1, lines 18-30. Therefore, since Frantzen teaches that it was known to use Nitinol in the art for similar devices as a substitute for Palmaz stainless steel materials, it would have prima facie obvious to substitute the same in Marin et al for the same reasons that Frantzen does the same.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Art Unit: 3738

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9301.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic
Primary Examiner
Art Unit 3738